

METHODS FOR TREATING OSTEOLYTIC BONE LESIONS

2

Field of the Invention

4 This invention is generally related to osteolytic bone lesions and more
5 specifically related to osteolytic bone voids that may develop as a result of
6 particulate debris that can collect around orthopedic implants. The invention is
7 exemplified by an embodiment in which an osteolytic bone lesion around an
8 implanted hip stem is treated.

Background of the Invention

10 It is often seen as inevitable that a patient, having undergone a total hip
11 replacement (at least on the femoral side of the joint), will at a later point in life
12 have to undergo a revision operation. Furthermore, even a revision hip may later
13 need to be further revised. The outcome of each revision surgery typically
14 results in lower quality of life for the patient.

15 One possible reason the revision may be needed is due to the
16 development of an osteolytic lesion between the implant and adjacent healthy
17 bone. These lesions or bone voids, which are often soft and spongy and not
18 supportive of the implant, can cause a well-fixed implant to loosen. To treat this
19 situation, the old implant is removed, the lesion cleaned out by debriding the local
20 area, and then a larger "revision" implant put in.

21 This phenomena of osteolytic lesions can occur in many other body
22 locations where implants have previously been implanted, e.g., humerus, tibial
23 plateau (knee), distal femur (knee), acetabulum, etc. Accordingly, the need to

1 treat osteolytic bone lesions after joint replacement surgery can be widespread.

2 Therefore, there is a continued need for improved treatments for osteolytic
3 lesions. Accordingly, there is room for improvement within the art.

4 **Summary of the Invention**

5 It is an object of the invention to provide an improved treatment for
6 osteolytic bone lesions.

7 It is an object of the invention to provide an improved treatment for
8 osteolytic bone lesions that does not require removal of the previous implant.

9 It is an object of the invention to provide an improved treatment for
10 osteolytic bone lesions, wherein the treatment is a minimally invasive technique.

11 These and other objects are achieved by a method of treating an
12 osteolytic bone lesion, comprising the steps of: making a first hole in the bone
13 adjacent the bone lesion; making a second hole in the skin and bone adjacent
14 the bone lesion; attaching a source of negative pressure to the second hole;
15 attaching a source of fluid to the first hole; injecting the fluid through the first hole
16 and into the bone; and whereby the fluid mixes with the bone lesion and both the
17 fluid and bone lesion are sucked out of the bone through the second hole, by the
18 negative pressure.

19 **Brief Description of the Drawings**

20 Figure 1 shows an exemplary body part, namely the proximal femur,
21 subject to osteolysis.

22 Figure 2 shows an exemplary body part, namely the proximal femur,
23 subject to osteolysis, and undergoing a step in the process according to the

1 invention.

2 Figure 3A shows an exemplary body part, namely the proximal femur,
3 subject to osteolysis, and undergoing an optional step in the process according
4 to the invention.

5 Figure 3B shows an exemplary body part, namely the proximal femur,
6 subject to osteolysis, and undergoing a step in the process according to the
7 invention.

8 Figure 4 shows an exemplary body part, namely the proximal femur,
9 subject to osteolysis, and undergoing another step in the process according to
10 the invention.

11 Figure 5 shows an alternative embodiment of how the various lines can be
12 connected to the bone undergoing the process.

13 **Detailed Description of the Drawings**

14 An exemplary embodiment of a method for treating osteolytic bone voids
15 that meets and achieves the various objects of the invention set forth above will
16 now be described.

17 Figure 1 shows an exemplary body part, namely the proximal femur,
18 subject to osteolysis. This exemplary body part is merely used for convenience.
19 However, the concepts of the instant invention may be applied to any body part
20 undergoing osteolysis, even those that were not subject to prior implant surgery.
21 For example, areas of the body subject to osteolytic bone lesions in the form of
22 unicameral bone cysts may also be treated by the inventive method.

23 In Figure 1, a hip implant I has been surgically implanted into the proximal

1 femur (hip) 100. Typically, this surgery will have happened in the past. The
2 details of hip implant I are irrelevant to the method of this invention and the
3 implant may come in any form, e.g., fixed, modular, primary, revision, ceramic
4 head, metal head, etc.

5 In non-diseased portions of hip 100, implant I is well-fixed between cortical
6 bone 110 and cancellous bone 120.

7 In a diseased portion of hip 100, osteolytic lesion 200 takes up space that
8 would normally be filled with cancellous bone 120. Lesion 200 is often soft and
9 spongy. Though lesion 200 is depicted in this exemplary embodiment as being
10 in the area of the proximal stem, it could just as easily have been in the area of
11 the distal stem.

12 In any event, as lesion 200 will, in most instances be surrounded by at
13 least cancellous bone 120, and usually also cortical bone 110, treatment is
14 significant and invasive because it has previously involved removal of the implant
15 I, debridement of the lesion area (which enlarges the intramedullary area even
16 further), and implantation of the revision implant. This is typically not done as a
17 minimally-invasive procedure.

18 Applicants have come up with a minimally-invasive approach to treating
19 these lesions that no longer require removal of implants and immediate revision.
20 Accordingly, the patient has a longer period of time between surgeries,
21 undergoes prolonged improved quality of life, etc.

22 An exemplary application of the method according to the invention is
23 shown in Figures 2-4, with relation to an osteolytic lesion in the hip.

1 In Figure 2, after the lesion 200 has been identified by any conventional
2 means (x-ray, fluoroscope, etc.), first and second holes 150 and 160,
3 respectively, are made through the patient's skin (not shown) and cortical bone
4 110 adjacent the lesion 200.

5 Second hole 160 will be attached/connected to a conventional negative
6 pressure source, such as a suction source (not shown) via suction line 300.
7 Typically, the conventional suction source will be the wall suction. However, the
8 suction source may be any vacuum pump. Furthermore, while suction line 300
9 will typically be attached to second hole 160 via threads 160' drilled into cortical
10 bone 110, (Figure 5), there is no such requirement. Suction line 300 may be
11 attached to hole 160 by any means. Though suction line 300 itself will typically
12 be a cannula with a luer lock for further connection to tubing T or a syringe, it
13 may comprise tubing.

14 First hole 150 will first be attached/connected to a fluid source (not shown)
15 via fluid line 400. Typically, the fluid source will be a saline containing syringe
16 375. However, the fluid source may be a saline pump. Furthermore, while the
17 fluid has been discussed as saline, it need not be. Any medically accepted fluid
18 useful for flushing clean a lesion site may be used. Fluid line 400 can also be
19 attached to first hole 150 via threads as described with respect to the vacuum
20 line and second hole 160. However, fluid line 400 may be attached to first hole
21 150 by any means. Though fluid line 400 itself will typically be a cannula with a
22 luer lock for further connection to tubing T or a syringe, it may also comprise
23 tubing.

1 All cannulae may be radially ported for 360 degree delivery of material, as
2 well as for delivery in an axial direction. Furthermore, for complicated
3 anatomical areas, the cannulae may be positioned using conventional guide
4 wires and fluoroscope.

5 Fluid is then injected through fluid line 400, through first hole 150, and into
6 the lesion 200 area. Fluid is injected at sufficient pressure that when combined
7 with the suction from suction line 300, the fluid will easily make its way into the
8 lesion area yet not result in the pressurization of the fluid into, for example,
9 nutrient vessels, e.g., emboli. The moving fluid begins to break up the soft lesion
10 200 and fragments 210 of the lesion 200 become entrained in the fluid. Fluid and
11 entrained lesion fragments 210 begin being sucked out of the bone through the
12 suction line 300. This flow is continued until the suction line 300 is clear of lesion
13 fragments 210.

14 At this point, optionally, the above process can be repeated with the fluid
15 line 400 attached to second hole 160 and the suction line 300 attached to first
16 hole 150 to provide yet further flushing of the lesion site. Optionally, the process
17 of switching the fluid and negative pressure lines may be repeated multiple times.

18 Note calling the various holes 150, 160 "first" and "second", is merely for
19 convenience and intended to have no limiting effect. Furthermore, though the
20 suction line 300 is shown as being below the fluid line 400 during the first
21 fragment flush, there is no preferred or required order or orientation and indeed,
22 much depends on the size and shape of the lesion itself. Furthermore, if the two
23 holes are too far apart, it is possible that the fluid pressure inside femur 100 can

1 become excessive causing a fracture of the cortical bone 110.

2 Finally, in the case of lesions that are not soft and spongy, but dense or
3 containing a membrane, an additional step may be required. As shown in Figure
4 3A, a conventional rotating wire wisp W or similar device, will be used to
5 macerate the lesion 200 so that it can be flushed. This wire wisp W can be
6 inserted into the lesion area via either of first or second hole 150, 160, and either
7 of line 300 or 400, and therefore there is no need to prepare another incision or
8 make a larger incision. Minimally invasive surgically devices useful for making
9 cavities inside body tissue are extremely well known, see e.g., U.S. Pub. No.
10 2003/0055316, U.S. Patent No. 6,328,251 and patents cited therein, all of which
11 are incorporated by reference herein.

12 Figure 3B depicts the post-flushing/macerating stage of the method. The
13 lesion 200 area is now replaced with an empty space/void 230.

14 Figure 4 depicts the void-filling stage of the method. During this stage of
15 the method, preferably a bioabsorbable material is introduced through the first
16 hole 150 and into the bone. As will be described below, not only will this material
17 temporarily fill the void, it will also be the source of new bone growth in the void
18 area.

19 A source of bioabsorbable material B is provided. Typically,
20 bioabsorbable material B will be contained within a conventional syringe 600
21 having a plunger 610. However, it is possible to use a mechanically-pumped
22 source of material. It is preferred that syringe 600 would be brought into fluid
23 contact with void 210 by connecting the conventional screw end on the end of

1 syringe 600 with the luer cap 410 on the end of fluid line 400. However, it is
2 possible that fluid line 400 can be removed and a needle attached to syringe 600
3 and the tip of the needle inserted directly into hole 150. The benefit to using fluid
4 line 400 is that it then becomes possible to fill the void with bioabsorbable
5 material from both holes without having to remove the suction line 300 from one
6 hole and move it to the other.

7 The bioabsorbable material would be injected according to its label
8 instructions and when combined with the suction from suction line 300, will easily
9 make its way into the void area. The injection process may be carried out using
10 fluoroscopic guidance or percutaneously.

11 The preferred bioabsorbable material B is an injectable form of calcium
12 sulfate (CaSO_4) known as MIIG™, sold by Wright Medical Technology, Inc. of
13 Arlington, Tennessee, the assignee of the present patent application. This
14 material has superior compressive strengths, completely resorbs, regenerates
15 bone, and is capable of passing through very small gauge needles with manual
16 pressure. The materials underlying this product are described in, for example,
17 U.S. Published Patent Application 2003/0185903.

18 Other possible bioabsorbable materials may be injectable forms of:
19 calcium phosphate, tri-calcium phosphate, hydroxyapatite, coral hydroxyapatite,
20 demineralized bone matrix, and mineralized bone matrix. Furthermore, the
21 bioabsorbable material may be an injectable form of a biopolymer, for example,
22 polylactic acid, polyglycolic acid, polygalactic acid, polycaprolactone,
23 polyethylene oxide, polypropylene oxide, polysulfone, polyethylene,

1 polypropylene, or hyaluronic acid, bioglass.

2 Though preferably the material is bioabsorbable, it is also possible that the
3 material be merely bioimplantable, e.g., hydroxyapatite or PMMA. Material
4 selection is based on the application.

5 Finally, as mentioned with respect to wisp W, it should be noted that prior
6 to the injection of the bioabsorbable material B, it is possible to use arthroscopic
7 shaving tools to go in through either of fluid or suction lines 400, 300 and further
8 clean the lesion site if the doctor so desires. By using injectable biomaterials,
9 eventhough small needle sizes are used, it is still possible to pass arthroscopy
10 tools through them or at least through openings 150 and 160 and therefore not
11 require more invasive surgery.

12 While the invention has been described with respect to a preferred
13 embodiment and certain variations, the invention is not so limited and reference
14 should be made to the appended claims.